

REMARKS

Claims 1, 3-8, 36 and 37 are pending. Claim 1 has been amended to include the features of claim 35, which is in turn canceled. Claims 21 and 37 are canceled as they would no longer further limit the claims from which they depend.

Rejection under 35 USC § 112, second paragraph

Claim 6 is rejected under 35 USC § 112, second paragraph, as allegedly being indefinite in the recitation of "partial" inhibition of cleavage of Protective Antigen by trypsin. Claim 6 is amended to remove the term "partial" thereby obviating this rejection.

Rejection under 35 USC § 112, first paragraph

Claims 1, 3-8, 21 and 35-38 stand rejected under 35 USC § 112, first paragraph, for alleged lack of written description of the claimed invention. In particular, the Examiner asserts that the specification fails to describe proteins of the invention other than one isolated from *Imperata cylindrica*.

Applicants disagree for all of the reasons that have been explained previously. Nonetheless, to advance the prosecution of this application, claim 1 is amended to recite that the protein is one isolated from *I. cylindrica*, thus overcoming the rejection. Applicants reserve the right to file an application directed to the broader subject matter pursuant to 35 USC § 120.

Rejections for anticipation

Claims 1, 3-8, 21 and 35-38 stand rejected under 35 USC § 102(a) as being anticipated by Bijli et al. (2003), under 35 USC § 102(b) over Bijli (2002) and under 35 USC § 102 (b) over Verma (2000). These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants reiterate that all of the references cited disclose a 67 kDa protein that is identified in an SDS-PAGE gel solely by molecular weight. As has previously been argued, the one-dimensional SDS-PAGE gel is well-known by one of ordinary skill in the art to provide separation solely by molecular weight (actually by charge/mass ratio of denatured protein, which

is proportional to the log of molecular weight). Furthermore, there is of record evidence provided by the Declaration of Naveen Arora that attests to the differences between the protein of the present invention and that disclosed by the cited references.

The Examiner must recall that for a rejection under 35 USC § 102 to be correct, the molecule disclosed (as composition of matter claims are at issue) must be identical to that claimed. In the present instance, at least two differences exist between the proteins disclosed in the references and the protein presently claimed.

First, the protein disclosed in the cited references has an amino-terminus that is blocked. For whatever reason that this has occurred, the amino-terminal sequence of such "isolated" protein as disclosed by Verma (2000) cannot be determined by Edman degradation. To the degree that the Examiner alleges that the proteins of Bijli (2002) and Bijli (2003) are the same, because they are obtained from the same grass and have the same molecular weight, then the proteins disclosed in these references must also be considered to have a blocked amino-terminus. On the other hand, the protein of the instant invention is readily sequenced by this process. These facts are clearly established by the Declaration of Naveen Arora, and they establish a plain difference in the chemical nature of the protein disclosed in the cited references, or at least Verma (2000), and the protein of the instant invention.

Applicants have met their burden of demonstrating a physical difference in the protein disclosed in Bijli et al. (2003), Bijli (2002) and Verma (2000). Accordingly, the rejections for anticipation over these references should be withdrawn.

The Examiner commits legally reversible error in requiring that Applicants "need[s] to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant[s'] product in order to overcome the aspect of the product's purity relied upon."

First, the Examiner is applying a standard, i.e. a showing of unexpected results, that represents Applicants' burden of proof to overcome *prima facie* obviousness. This is not the

standard for overcoming a rejection for lack of novelty, which merely requires a demonstration of some difference between the composition of the invention and the composition of the prior art.

Second, the Examiner is mistaking Applicants' arguments about the chemical difference at the amino-terminus as one about purity. That is incorrect. The distinction argued at the moment is about the chemical nature of the amino terminus of the "isolated" protein that is obtained following the procedures described in the references versus the procedures described in the instant application. This is not a question of purity of the product obtained as the isolated protein.

With respect to the "purification" described by both Bijli references, such is only by SDS-PAGE, which is well-known in the art to denature (i.e. unfold) proteins and so to inactivate them. On the other hand, the present claim 1 recites the following activities of the isolated protein:

- (vi) inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner,
- (vii) binds to IgE.

Claim 1 further recites that the protein is resistant to cleavage by trypsin.

One of ordinary skill in the art would understand that the biological activities (vi) and (vii), and the biochemical property of trypsin resistance, would require that the protein of the invention be in a "native" form, at least not denatured by the detergent added to the SDS-PAGE used for analysis (= isolation according to the Examiner) in the Bijli references. Again, this is not a question of the degree of purity, but rather a matter of the physical form of the protein. And once again, such distinction in the physical form of the claimed protein is sufficient to establish novelty over the proteins described in the cited references.

To the degree that the Examiner suggests that the "isolated" protein of the invention lacks any utility not shared by the protein as it exists in a pollen grain or crude extract as in the Bijli references, Applicants point out the therapeutic activity as an Anthrax anti-toxin set forth on page 13 of the specification. The Examiner presents no evidence that the crude preparations or whole pollen grains (i.e. the compositions prior to "purification" of a 67 kDa protein) described

in any of the cited references have Anthrax anti-toxin activity or would be commercially acceptable for such use.

For all of the above reasons, as well as those proffered previously, Applicants submit that the presently claimed invention is a physically distinguishable molecule from the protein mixtures or SDS-PAGE analyzed proteins of Bijli (2002) and Bijli (2003), and from the chromatographically purified protein described by Verma (2000). Accordingly, the rejections for anticipation over these references should be withdrawn.


In view of the above, Applicants respectfully submit that the present claims define allowable subject matter. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims

If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP, at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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